



MANAGEMENT OF YMP-LBNL ELECTRONIC DATA

PROCEDURE ID: YMP-LBNL-QIP-SV.0

REV. 2, MOD. 1

EFFECTIVE: 03/21/2002

1. PURPOSE

This Quality Implementing Procedure (QIP) describes the controls to be applied to the electronic management of data, including developed or acquired data, produced for scientific investigation or performance assessment technical products developed for the Yucca Mountain Project (YMP) at Lawrence Berkeley National Laboratory (LBNL).

2. SCOPE

This QIP applies to quality assurance (QA) work activities for the YMP at LBNL based on the evaluation process performed to meet AP-SV.1Q, *Control of the Electronic Management of Information*. This procedure applies when electronic media are relied upon for the control and access to data that are acquired, developed, or used during any phase of analysis, process control, or scientific investigation for a technical product.

The controls to be applied to developed or acquired data shall be implemented as described herein. This procedure contains the standard processes to be implemented; if the controls are to be further implemented in a TIP or scientific notebook, the TIP or scientific notebook will expand or elaborate on these processes.

Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with AP-SI.1Q, *Software Management*. The acquisition, development and use of preliminary data are an inherent part of the scientific investigations and are controlled by AP-SIII.1Q, *Scientific Notebooks*.

3. PROCEDURE

3.1 Accuracy, Completeness and Integrity of Data

YMP-LBNL utilizes the Technical Data Management System (TDMS) for storage, retrieval, and maintenance of electronic data that support technical products. Data are transferred to and/or subsequently retrieved from the TDMS and incorporated within a technical product. The accuracy, completeness, and integrity of the data shall be verified by the originator of the technical product and through the review and checking requirements of the applicable QA procedures.

Raw field or laboratory data shall not be submitted to the TDMS, however they will be submitted to the Records Processing Center (RPC). The first

step of maintaining the integrity of the raw data in their preliminary form is the calibration of the equipment. Equipment failure or out of calibration conditions shall be addressed according to AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards*. The integrity of the preliminary data during transfer to local storage is covered in Section 3.2, and for storage before submittal to TDMS in Section 3.3.2.

Data transfer and storage requirements listed in Sections 3.2 through 3.5 below necessitate that certain details concerning the data files are to be recorded in the scientific notebooks. Because the information to be recorded may be the same for many of the data files used, Attachment 1 is provided as a convenient means to summarize the information that applies to most data files. For data files that require different or additional information, the corresponding information shall be recorded in the appropriate scientific notebook entry. If Attachment 1 is not used, the same information shall be recorded in a scientific notebook or in documentation associated with the data and traceable to the data.

3.2 Data Transfer

YMP-LBNL scientific staff commonly transfer preliminary data electronically employing the means listed in the subsections below.

The following methods are used to ensure the accuracy and completeness of preliminary data transfer in an electronic system.

The ethernet (see Section 3.2.3) is an electronic interconnection from one computer to another over dedicated lines. This is only a path of transfer, not a method.

3.2.1 Transfer of Data from Hard Copy to Computer Disk

The scientific staff entering data from hard copy to an electronic format or comparing data on hard copy to an electronic format shall include an entry in the scientific notebook indicating that verification of input from the hardcopy to the computer file holding the input data has been conducted. The scientific staff shall indicate this verification by performing the following:

- visually comparing the hard copy data to the data as displayed on the monitor of the computer;
- reconciling any differences to make the two identical;
- including in the scientific notebook entry
 - the source of the data
 - the filename of the electronic input data
 - signature and date (or initials and date) for the scientific notebook entry to indicate that the verification was performed.

3.2.2 FTP via the Internet

FTP via the internet has proven to be a dependable process for file transfer between two locations. Historically, if there are problems (which are rare) that occur during transfer, the end user knows the problem exists and is able to either request retransfer of the file requested or, if that is not possible, obtain the file by another means. Since FTP has been found to be dependable, there will be no further controls placed on the process.

3.2.3 Data Transfer from Data Logger to Computer Disk via Modem or Ethernet

File transfer from data logger to computer disk via modem or an ethernet has been found to be dependable. The type of information obtained by the data logger and transferred to the computer is well known to the investigator. Frequent inspection and evaluation of the process being monitored by the data gathering equipment at the location where the information is gathered and intimate knowledge of the data points expected gives the investigator confidence in the information transferred to the computer. Since spurious data are known to the investigator and evaluation of the end results is performed by technical review, no further controls outside the professional judgement of the investigator and the required reviews of the resulting data will be applied to this transfer method.

3.2.4 File Transfer from Disk to Disk

File transfer from disk to disk has proven to be dependable for the media used at YMP-LBNL, e.g., 3½" disk, CD, zip disk, tape, hard drive, etc. Since the file information is known from the source medium by name and date, and usually size, the target medium will be checked visually for correct information in the log created during transfer. Also, the operating system on the computer being used has adequate process controls; any transfer problems are obvious to the user such that the transfer process will be performed with a caution or warning supplied by the system. The professional judgment of the user will be relied upon with no further controls placed on the process.

3.2.5 E-mail

This process shall be controlled by the user assuring that the sending and receiving e-mail applications are compatible in their encoding and decoding methods. File transfer through e-mail has been found to be dependable once the issue of compatible encoding/decoding

has been resolved. A (one-time) trial file transfer between the subject computers shall be made employing the e-mail application(s) to be used later. The data shall be verified as correct by visual inspection, and the successful transfer shall be recorded (once) in a SN entry, including:

- the recipient,
- the filename,
- the date (indicated by scientific notebook entry date), and
- a statement to the effect that a correct transfer was accomplished.

Following this, the professional judgement of the user will be permitted with no further controls placed on the process.

No e-mail transfer of data to or from other YMP sites to YMP-LBNL shall be employed in QA work activities. The data must be formally requested and transferred in accordance with AP-3.15Q, *Managing Technical Product Input*.

3.3 Data Storage and Maintenance

3.3.1 Data Storage Media

Only preliminary data are maintained by YMP-LBNL. Typical storage media include computer hard drives, CDs, floppy disks, tape, zip drive, and file servers, all maintained in the protection of an indoor environment. These media are considered adequate for data storage for the typical retention time (e.g., up to one year) of the data before they are submitted to TDMS or the RPC. The operating system on the computer, including servers, where the preliminary data are being stored has adequate process controls such that disk transfer problems are obvious to the user, reporting a caution or warning if the transfer to disk is incorrect. For CDs, floppy disks, tape, zip drives, etc., the media have been found to retain retrievable and accurate data for several years, much longer than the one-year retention time needed before submitting the data to TDMS. Concerning the original recording of such media, see Section 3.3.2.

Data supporting technical products are submitted to the TDMS according to requirements of the applicable QA procedures (i.e. AP-SIII.3Q, *Submittal and Incorporation of Data to the TDMS*, AP-SIII.9Q, *Scientific Analyses*, AP-SIII.10Q, *Models*, AP-3.11Q, *Technical Reports*, etc.). Upon acceptance of the data, the TDMS maintains and stores the data according to applicable procedures.

3.3.2 Methods of Data Storage and Verification of Data Integrity

The method of data storage shall be determined by the **scientific staff** considering access controls, location of the data, storage medium, security, and protection of the storage medium from deleterious conditions such as extremes of temperature, humidity, etc., and the desired retention time of the data. The method of storage shall be recorded in a scientific notebook (Attachment 1 may be used for this purpose).

Following data storage, the integrity of the data shall be verified through the standard backup system, as applicable (see below), provided by LBNL/ESD (Earth Sciences Division) for backing up computer systems. The information for each data file (see Section 3.3.3) is given in the initial scientific notebook entry where it is recorded. The LBNL/ESD standard backup system has been found to be dependable and the associated utility software has inherent verification functions to ensure the integrity of the electronic data files. The copying utilities produce logs with error messages to the operator if an error occurs during storage of the data. The operating system performing the data transfer has the same warning messages from the system as mentioned above in Sections 3.2.2 and 3.2.4. Over many years, scientists have been able to recover files that were accidentally deleted or were damaged; backup copies of files are kept for more than one year so that recovery is available through the retention time of the preliminary data before they are sent to TDMS.

If the data files are stored on storage devices (e.g., zip drives) or media (e.g., CDs) that are not subject to the standard backup system for LBNL/ESD, the scientific staff shall verify (see data transfer verification in Section 3.2, including verifying as correct by visual inspection) the integrity of such data and record that verification is successful in a scientific notebook entry subsequent to the transfer.

3.3.3 Maintenance of Data Files (Data Traceability and Retrievability)

To enable both traceability and retrievability, the **scientific staff** shall document the following information for data files supporting technical products:

- the file identification (indicating full pathname for the file),
- origination date,
- the originator of the file, and

- the computer or other storage device or medium on which it resides.

This information shall be recorded or referenced in the scientific notebook. When data are determined to support a technical product, the data shall be transferred to the **Technical Data Coordinator or designee** to submit to the TDMS (see section 3.6) in accordance with AP-SIII.3Q.

For data files that support a technical product, scientific staff shall maintain traceability to the document they support (e.g., a Scientific Analysis, Model, Technical Report). One reference can be made for a group of files that support the same technical product.

3.3.4 Data File Identification and Labeling

Files stored shall be identified as follows:

- the source of data (e.g., computer ID, directory, instrument ID),
- date of file,
- type of medium (e.g., hard disk, CD, floppy disk, etc.),
- file format, which may be indicated by a file extension such as *.txt for plain text, *.rtf for rich text, *.xls for Excel spreadsheet, *.jpg for JPEG (images), *.htm for HTML, etc. (where the "*" indicates the filename), and
- retention time (see Section 3.3.1).

A general statement of common features (e.g., file source, file type, file format, and retention time) may be given for a group of files that share those features. This information will be recorded in the scientific notebook.

3.4 Equipment Access and Backup

Physical access to equipment used in maintaining preliminary electronic data (e.g., file servers, workstations, personal computers, instruments) is controlled by limited access to LBNL. Access to LBNL is controlled through the main gates, where posted security personnel screen employees and visitors. Moreover, the buildings/facilities are locked during off-hours. The **scientific staff** shall maintain a list of each person(s) with controlled access to the information system in their scientific notebook as described in Section 3.5 (see also Attachment 1, last bullet).

Equipment maintaining YMP-LBNL preliminary electronic data shall be backed up at a frequency determined by the **scientific staff**. Standard back-up systems shall be used whenever possible (see Section 3.3.2). Documentation of the backup shall be recorded in the scientific notebook (see Attachment 1, fifth bullet). If the nature of the data, the equipment or the scientific investigation requires additional back up requirements, they will be listed in a TIP or scientific notebook.

3.4.1 Servers

Servers that have preliminary data shall have an established backup process. Backup media shall be labeled and stored with appropriate means depending on the media.

3.4.2 Workstations/Personal Computers

Computers with preliminary data shall have a backup process to ensure the data are protected from loss. Backup media shall be labeled and stored with appropriate means depending on the media.

3.4.3 Instruments

Data from instruments that have data shall be copied to a backup medium, which shall be appropriately labeled and stored. Any hard copy printouts shall be kept until the backup copies are appropriately verified (see data transfer verification methods in Section 3.2).

3.5 Security of Data

To ensure the security and integrity of the preliminary data, the **scientific staff** shall maintain a list in a scientific notebook (see Attachment 1, last bullet) of each staff member or group of staff members with access to the electronic data and the computers on which it resides to ensure the security and integrity of the data. This list shall include:

- identification of the computers, including servers; for other storage devices or media, the location shall be specified,
- name of the individual(s) or group(s),
- type of access (read only, read/write), and how controlled,
- signature of the individual approving such access, and
- date of approval for access (see Attachment 1).

Servers and workstations/personal computers shall be accessible only to authorized personnel with proper authentication (e.g., a password).

3.6 Transfer of Data to the TDMS

Upon technical review of data supporting a technical product, the **scientific staff** shall transfer the data and associated records to the **Technical Data Coordinator or designee**. The following items shall be submitted:

- subject data identified with constraints, limitations, or assumptions, and
- a readme file or a memo containing a listing of all data files with: file identification, operating system, and a reference to the technical product where these data were used or for which these data were produced.
- Data review materials (in accordance with YMP-LBNL-QIP-6.1, *Document Review*).

The **Technical Data Coordinator or designee** shall transfer these data following one or more of the methods of Section 3.2, employing file compression, to the appropriate medium for submittal (e.g., CD, 3½" disk, tape, etc.). The file compression utilities have been found to be compatible with utilities employed by TDMS. After transfer to the medium, the **Technical Data Coordinator or designee** shall assure the original data identification as transferred is the same as those obtained from the sender or originator. The data shall then be submitted to the TDMS by the **Technical Data Coordinator or designee** in accordance with AP-SIII.3Q.

4. RECORDS

4.1 QA Records

Scientific Notebooks as controlled by AP-SIII.1Q

YMP-LBNL Review Record (YMP-LBNL-QIP-6.1, Attachment 2)

YMP-LBNL Applicable Reference Information (YMP-LBNL-QIP-6.1, Attachment 3)

YMP-LBNL Comment Sheet(s) (YMP-LBNL-QIP-6.1, Attachment 4)

Key Technical Data Traceability (YMP-LBNL-QIP-6.1, Attachment 6)

4.2 Non-QA Inclusionary Records

Copy of data submittal package

Copy of TDIF(s)

Copy of notification by e-mail or letter showing non-submittal of data to TDMS

4.3 Non-QA Exclusionary Records

None

5. RESPONSIBILITIES

- 5.1 **Scientific Staff** are responsible for meeting the requirements of this procedure regarding the transfer and storage of preliminary data and data files and their submission to the TDMS and RPC.
- 5.2 The **Technical Data Coordinator or designee** is responsible for preparing and submitting data to the TDMS in accordance with AP-SIII.3Q.
- 5.3 The **Records Coordinator or designee** is responsible for submitting the records/data associated with this procedure to the YMP RPC, in accordance with AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

CD	Compact Disk
DOE	Department of Energy
EA	Engineering Assurance
ESD	Earth Sciences Division
ESF	Exploratory Studies Facility
FTP	File Transfer Protocol
ID	Identification
LBNL	Lawrence Berkeley National Laboratory
OQA	Office of Quality Assurance
PI	Principal Investigator
QA	Quality Assurance

QARD	Quality Assurance Requirements and Description
QIP	YMP-LBNL Quality Implementing Procedure
RPC	Records Processing Center
SN	Scientific Notebook
TDIF	Technical Data Information Form
TDMS	Technical Data Management System
TIP	YMP-LBNL Technical Implementing Procedure
YMP	Yucca Mountain Site Characterization Project

6.2 Definitions

Data: As it pertains to Supplement III, information developed as a result of scientific investigation activities, including information extracted from reference sources, and performance assessment analysis (QARD).

Data File: An organized collection of related information, usually arranged in logical records that are stored together and treated as a unit; related numeric, textual, or graphic information that is organized in a strictly prescribed form or format (AP-SV.1Q).

Electronic Media: A form of media used to store, maintain, or transmit information that only a computer or other electronic device can read or process. Such media would include floppy disks, optical disks, hard drives, magnetic tape, etc. (AP-SV.1Q).

Preliminary Data: Acquired or developed data that have not received a technical review that establishes and documents the technical validity of the data (AP-SIII.3Q).

Quality Implementing Procedure: Each QIP describes an aspect of the YMP-LBNL implementation of YMP QARD requirements.

Raw Data: Field or laboratory data that have not been converted to or do not occur as scientific or engineering terms as identified in the online Technical Data Parameter Dictionary. Raw data are not submitted to the TDMS (AP-SIII.3Q).

Scientific Staff: Any scientist, engineer, research or technical associate, technician, or student research assistant performing quality-affecting work for YMP-LBNL.

Technical Implementing Procedure: Each TIP describes YMP-LBNL technical and/or scientific tasks that are repetitive and standardized.

Technical Products: Any document containing engineering or scientific data with relevance to the characterization, design, licensing, construction, or operation of the Civilian Radioactive Waste Management System (e.g., analyses, calculations, models, technical reports, data submittal packages).

7. REFERENCES

AP-3.11Q, *Technical Reports*

AP-3.15Q, *Managing Technical Product Input*

AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*

AP-SI.1Q, *Software Management*

AP-SIII.1Q, *Scientific Notebooks*

AP-SIII.3Q, *Submittal and Incorporation of Data to the TDMS*

AP-SIII.9Q, *Scientific Analyses*

AP-SIII.10Q, *Models*

AP-SV.1Q, *Control of the Electronic Management of Information*

AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards*

YMP-LBNL-QIP-6.1, *Document Review*

8. ATTACHMENTS

Attachment 1, Supplement V Summary for Scientific Notebooks

9. REVISION HISTORY

07/09/99 – Revision 0, Modification 0:

Initial issue. YMP-LBNL-QIP-SV.0 is issued to implement the process results of evaluation required by AP-SV.1Q.

02/08/00 – Revision 1, Modification 0:

Incorporates changes to address QARD Revision 9 storage and security requirements.

11/10/00 – Revision 2, Modification 0:

Complete rewrite to streamline processes, incorporate standardized practices, and address the most recent changes to AP-SV.1Q.

03/21/02 – Revision 2, Modification 1:

Modification to update the required APs. Eliminate requirement for the Technical Data Coordinator to maintain a log of data submitted to the TDMS. Other format changes.

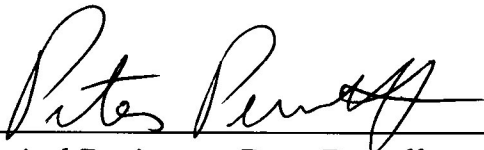
10. APPROVAL



Preparer: Vivi Fissekidou

3/21/02

Date



Technical Reviewer: Peter Persoff

3/21/02

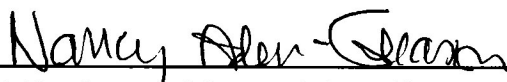
Date



Technical Reviewer: Robert Terberg

3/21/02

Date



EA Reviewer: Nancy Aden-Gleason

3/21/02

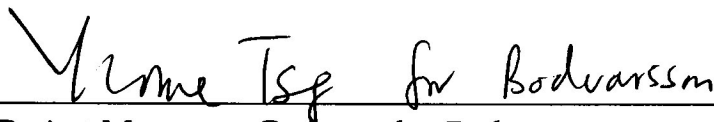
Date



BSC QA Concurrence: Stephen Harris

3/21/02

Date



Project Manager: Gudmundur Bodvarsson

3/21/02

Date

Supplement V Summary for Scientific Notebooks
YMP-LBNL-QIP-SV.0, Rev. 2, Mod. 1
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LBNL SCIENTIFIC NOTEBOOK ID #: YMP-LBNL-_____
YMP ID #: SN-LBNL-SCI-_____-V__

The information below applies to each data file unless otherwise specified within the scientific notebook (SN) entry.

- **Originator of electronic data files:** _____
- **Residing computer(s) (including servers) for electronic data files** (enter DOE property IDs):

- **For electronic data file transfers:** *method(s) of transfer* are (check all that apply):
 - ☐ Disk to disk ☐ FTP ☐ Ethernet/Internet ☐ E-mail ☐ Other: _____
 - The information for each file is given in the initial SN entry where the file is recorded.
 - The *method(s) for verifying the integrity of the data* in the notebook identified below apply to each transfer (check all that apply): ☐ Random checks of data content ☐ Visual checks of file format
 - ☐ Checksums ☐ Other: _____
- **For information storage and maintenance of transferred or stored files:**
 - Media are protected from extremes of temperature, humidity, etc. by location onsite in an indoor environment. The type of medium is (check main type, identify others in SN entry): ☐ Hard drive, including server files
 - ☐ CD ☐ Floppy disk ☐ Tape ☐ Zip drive ☐ Other: _____
 - The *file format* is: ☐ plain text ☐ Excel spreadsheet ☐ rich text format
 - ☐ Other: _____
 - Specify any particular formats (e.g., JPEG, HTML, etc.) for specific files in the SN entry where the file information is recorded. The format may be indicated by the file extension appended to the filename.
 - The *retention time* is up to one year, to ensure enough time to transmit data supporting technical products to the TDMS.
- **For electronic data file backups:**
 - The *standard backup system* provided by LBNL/ESD for backing up computer systems is employed. The information for each file is given in the initial SN entry where the file is recorded.
 - The *method for verifying the integrity of the data backup* is the inherent verification functions incorporated into the backup process by the standard backup system.
- **For electronic data files recorded in this notebook, the security and access is as follows:**
 - Identify *type of access*: ☐ Read Only ☐ Read/Write
 - *Access is controlled* by password to computer system and/or off-hours locked building.
 - Individuals listed as *authorized personnel* on the Notebook Information page of this SN (including the PI) have access to the electronic data. (Additional personnel may be included with a SN entry or listed below.)

Signature _____ Date _____
 Scientific Notebook Owner